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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,490	07/11/2000	Fearghus O'Foghludha	9105-21-IP	2050

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EXAMINER	
HARTLEY, MICHAEL G	

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1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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EXAMINER

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Commissioner for Patents

The information disclosure statement (IDS) filed 02 August 2004 has been fully considered. An initialed copy of the IDS form 1449 is attached hereto for appellent's convenience and will be scanned into the system.

Michael G. Hartley
Primary Examiner
Art Unit: 1616

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040513

Application Number: 09/614,490
Filing Date: July 11, 2000
Appellant(s): O'FOGHLUDHA, FEARGHUS

Laura M. Kelley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/01/2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1 and 3-9 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7). The brief provides a statement that claims 3 and 5 do not stand or fall together with claim 1, 4 and 6-9, but provides no reasons in support thereof. It is the examiner's position that all the claims should stand and fall together and it is unclear to the examiner why claims 3 and 5 were grouped separately.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) References

5,163,896	***SUTHANTHIRAN***	***11-1992***
5,342,283	***GOOD***	***8-1994***
6,152,869	***PARK***	***11-2000***
2002/005485	***GRUNZE***	***5-2002***

(10) Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Suthanthiran (US 5,163,896).

Suthanthiran discloses an integral source material (i.e., a radioactive seed) comprising a nuclide wherein the nuclide is chemically bound to a polymer, see column 3-4. For example, the nuclide may be ^{32}P labeled polynucleotides (e.g., polyadenylic acid, polyguanylic acid, etc.) wherein the phosphorus would be in the chain of the polymer, see column 4, lines 4-9. The limitation of "activated by exposure to radiation" is essentially, a "product-by-process" limitation, which fails to specifically limit the device to differentiate over the Suthanthiran, since this patent discloses an integral source having all of the same

components as claimed, i.e., a nuclide which is a chemically bound constituent of a polymer chain of the integral source material, which is part of a radioactive enclosure, i.e., a radioactive seed. In product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The fact the nuclide was made by a process of being "activated by exposure to radiation" would not give rise to a product which is different from Suthanthiran, since a radionuclide is a radionuclide, regardless of how it is obtained (however, most radionuclides are prepared by exposure to radiation). The radioactive seeds include a rectangular substrate, see figure 1, as well as, radioactive walls, see figure 3 and may have both flexible (see column 6, lines 22-65) and rigid enclosures, such as, a titanium capsule, see column 7, lines 35+. The actual claimed product is the same as the product of Suthanthiran, since a nuclide that is "activated" into a radionuclide (as claimed) would be a radionuclide in the polymer chain, as the P-32 in a polynucleotide (multiple nucleic acids bound together) would be in the polymer chain, as in polynucleotides, the phosphorus is in the chain of the phosphate backbone.

Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Grunze (US 2002/0054851).

Grunze discloses an integral source, i.e., an artificial implant, comprising a nuclide that is a constituent in the polymer chain (the P is in the polymer chain), such as, a fluorine containing polyphosphazene, see paragraphs [0013] to [0016]. For the reasons set forth above, the limitation, "activated by exposure to radiation" does not differentiate over the prior art, as this a step in the method of preparation. The integral source material is used in implants, stents, etc., and is contained in plastics, metals, alloys, ceramics, etc., which would be both flexible or rigid, rectangular in shape, (i.e., a stent) and since the radiolabeled polymer is used as a coating, such devices would have radioactive walls, see paragraphs [0021]-[0026]. The product of Grunze is directly within the scope of the claims, as an "activated" nuclide would be a radionuclide, which is in the polymer chain of the product of Grunze.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Suthanthiran (US 5,163,896) or Grunze (US 2002/0054851) in view of either one of Park (US 6,152,869) or Good (US 5,342,283).

Suthanthiran and Grunze disclose an integral source material comprising a nuclide, wherein the nuclide is a constituent in the polymer chain, as set forth above.

Suthanthiran and Grunze fail to specifically disclose that the nuclide is one that is activated (e.g., made radioactive) after preparation of the source and that the source has checkerboard form (claim 5). However, it is well known in the art of radioactive source, that starting with an activatable isotope provides increased safety and preparation as shown by Park and Good and that checkerboard form is known format, as shown by Park.

Park discloses that the nuclide can be one that is activatable by irradiation to provide the advantage of preparing the source without having to manipulate radioactive material, thereby increasing both safety and ease of preparation, e.g., column 6, lines 30-48. Park also teaches that the stents may be in a checkerboard, see figures 2 and 3.

Good discloses radioactive source which may comprise various nuclides and teaches the use of nonradioactive isotopes which can be later activated into radioactive form as equivalents to radionuclides, e.g., to provide easier preparation, see column 3, lines 4+.

It would have been obvious to one of ordinary skill in the art to use a nuclide which is activatable in the radioactive polymer based radioactive source disclosed by Suthanthiran or Grunze because it is well known in the art that the use of a radioactivatable nuclide (e.g., a radionuclide precursor) may be

used in a radioactive source as equivalent to radionuclides for easier and safer preparation. One of ordinary skill in the art would have been motivated to use an activatable nuclide because it provides the clear advantages of increased safety in the preparation of the source, as well as, increased shell life (without radioactive decay concerns). Further, it would have been obvious to form the stents in a checkerboard form because the prior art teaches that this is a known and preferred means of distributing radioactive material on such stents, as shown by Park.

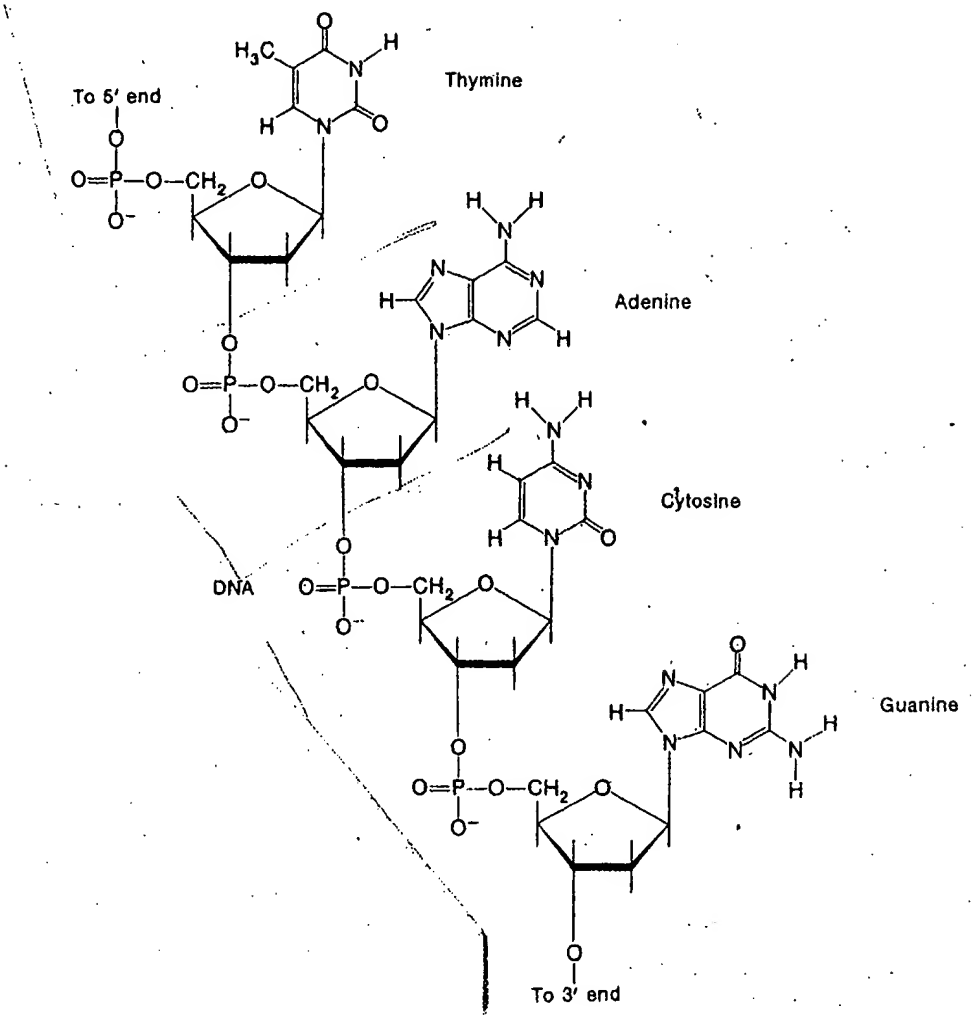
(11) Response to Argument

Claims 1, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Suthanthiran (US 5,163,896).

Appellant's arguments filed in the brief on 4/1/2004 have been fully considered but they are not persuasive.

Appellant asserts that Suthanthiran discloses products in which the nuclide is not part of the backbone of the polymer as claimed because the radioiodine is part of a pendent group. Appellant illustrates this by showing a formula disclosed by Suthanthiran which are monomers of amino acids (e.g., tyrosine) and states that the formula clearly shows that the radionuclide is a chemically bound substituent and not in the polymer backbone as claimed.

This is not found persuasive because Suthanthiran discloses that the source can comprise P-32 (phosphorus-32) polynucleotides, which are clearly a polymer having the nuclide as a constituent of the polymer backbone, as the phosphorus (P) atoms of a polynucleotide is in the chain or backbone of the polymer. A critical scientific issue that must be addressed in response to this argument is that polynucleotides are not polyamino acids. Polyamino acids are composed of amino acids monomers, while polynucleotides (which have a phosphate group) are composed of nucleotides that are bound through phosphate groups, (e.g., DNA). For clarification, the primary structure of DNA is provided below. A polynucleotide, for example, polyadenylic acid as disclosed by Suthanthiran would be the same except all of the bases would be adenine (instead of the thymine, adenine, cytosine and guanine as shown in the DNA molecule. But clearly, the phorphorus (P-32 as disclosed by Suthanthiran) is in the polymer chain.



Appellant further asserts that Suthanthiran fails to disclose a nuclide that is activated by exposure of radiation.

This is not found persuasive as the above rejected claims are product claims and the above argument referring to "activated" is a method step. A radionuclide, which has been activated, is the same as a radionuclide. The claimed product is drawn to a source comprising a radionuclide, which is taught the prior art. Note, in product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The fact the nuclide was made by a process of being "activated by exposure to radiation" would not give rise to a product which is different from Suthanthiran, since a radionuclide is a radionuclide, regardless of how it is obtained (however, most radionuclides are

prepared by exposure to radiation). The product disclosed by Suthanthiran, such as, a polynucleotide, (e.g., polyadenylic acid) would be the same as claimed as it would have a radionuclide in the polymer chain. The "activated" is relevant to a method of preparing, but not to the product. Note, the instant claims include P (phosphorus) as the nuclide, see claim 4.

Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Grunze (US 2002/0054851).

Appellant asserts that Grunze fails to disclose a nuclide that is activated by exposure of radiation.

This is not found persuasive for the reasons set forth above, namely the claims are product claims and the above argument referring to "activated" is a method step. In product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. Thus, the recitation of "activated by" cannot be used to differentiate over the cited art, as this is clearly a product-by-process limitation. Note, appellant's arguments of Grunze include discussion of "hot chemistry" methods; however, it is again noted that the presently appealed claims are not method claims, but are product claims. Appellant argues here that the methods of preparing differ, but this argument does not state how the product itself, as claimed, differs from the product of Grunze.

Appellant asserts that the polymer of Grunze is applied as a coating in the examples of Grunze and such coatings are on the nanometer or micrometer scale, which is different than the integral source as claimed.

This is not found persuasive because the claim states "an integral source material having..." Clearly, the polymer used in Grunze is within the scope of an integral source material as claimed. Further, this argument is not persuasive because Grunze clearly discloses that "The antithombogenic polymer according to the invention can, however, be used not only as a coating, but even as the complete material in particular applications, such as in their use as endovascular prostheses and the like, see page 2, [0022]. However, it is unclear how this argument is being used to differentiate over Grunze. The instant claims do not exclude such coatings. Grunze is drawn to radioactive devices, including stents,

implants, etc., which are clearly within the scope of, at least, "test objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures" as claimed. Also, these are more intended uses of the claimed source. The source as claimed requires a polymer and a nuclide (radionuclide) which is part of the backbone of the polymer. This is specifically disclosed by Grunze.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Suthanthiran (US 5,163,896) or Grunze (US 2002/0054851) in view of either one of Park (US 6,152,869) or Good (US 5,342,283).

Appellant asserts that there is no particular motivation or teaching to combine the teachings of either Suthanthiran or Grunze with Park or Good.

This is not found persuasive because all of the cited references are in the same field of endeavor, radioactive seeds, stents, implants, etc. This is further shown by the fact that all the patents cited include the classification of Class 600 Subclass 1-8, which is drawn to such radioactive devices that are implanted into the body. One performing endeavors in the art area would be motivated to consider all of the pertinent prior art in the field. Secondly, Park and Good both teach an improvement in this area, which is that such radioactive devices for implantation into the body can be made using a stable nuclide that is activated after formation of the device to provide the advantages of, 1) being able to prepare the device without having to work with radioactive substances (e.g., easier and safer preparation) and 2) avoiding radioactive decay of the radioactive implant prior to there use, since the prepared implant can be activated after it is made, but directly prior to it use. Clearly, one of ordinary skill in the art would be motivated to take advantages of such teachings that are in the same field of endeavor.

Appellant asserts that nothing in Park or Good suggests that post-irradiation could be successful to irradiate a nuclide that is a chemically bound constituent of the polymer backbone.

This is not found persuasive. The advantage disclosed by Park and Good is using a stable nuclide, which may later be irradiated to provide a radionuclide. This advantage would not be dependent on the position of the nuclide, for example, whether or not it was in the backbone or elsewhere in the

radioactive source. Obviousness does not require absolute predictability. The predictability of irradiating a nuclide to form radionuclide would be predictable to gain the advantage of Park and Good regardless of the position of the nuclide, as Park and Good do not suggest that the position of the nuclide is critical in irradiation. Further, the above claims are product claims. Thus, these claims do not require the actual steps that the source be formed and then irradiated. The only requirement is that a nuclide be activated. Park and Good clearly teach that nuclides, which are activated into radionuclides, may be used for such radioactive sources, such as, those disclosed by Suthanthiran or Grunze.

Appellant further asserts that the cited references fail to teach a checkerboard format.

The devices taught by Park suggest what is basically a checkerboard format with alternating areas of active and inactive sites.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Primary Examiner
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Michael G. Hartley
March 22, 2005

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